Remarks

The Office Action mailed 10 August 2005 has been received and reviewed. Claims 35-36, 46-66, and 71-73 are canceled, without prejudice, to further prosecution. Applicant reserves the right to prosecute the canceled claims in a continuing application. The pending claims are claims 30-33, 37-42, 44-45, and 67-70. Reconsideration and withdrawal of the rejections are respectfully requested.

Rejection of claims 37-40 and 67

Claims 37-40 and 67 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Barondess et al. (Nature, 344:871-874, 1990) as evidenced by Harlow et al. (Antibodies: A Laboratory Manual, Col Spring Harbor Laboratory, Chapter 5, p. 76, 1988) and Hunter (U.S. Patent 5,554,372). This rejection is respectfully traversed.

The Examiner asserts that claims 37-40 and 67 are inherently anticipated by Barondess et al., and that Harlow et al. or Hunter are used to show that every element of the claimed subject matter is disclosed by Barondess et al. (Office Action at page 7, first full paragraph). It is respectfully submitted that the rejection of claims 37-40 and 67 under 35 U.S.C. § 102(b) as being anticipated by Barondess et al. as evidenced by Harlow et al. and Hunter lacks an essential element required to establish a *prima facie* rejection. Specifically, Barondess et al. does not disclose the claimed composition comprising a pharmaceutically acceptable carrier, and Harlow et al. and Hunter do not show that Barondess et al. inherently disclose the claimed composition.

Independent claim 37 recites, *inter alia*,

> "An immunogenic composition comprising: an isolated nucleic acid molecule comprising a nucleotide sequence encoding a polypeptide comprising an avian *E. coli* Iss polypeptide or an immunogenic fragment or immunogenic subunit of the avian *E. coli* Iss polypeptide . . . and a pharmaceutically acceptable carrier."

Applicants have previously argued that Barondess et al. do not disclose the claimed composition comprising a pharmaceutically acceptable carrier (see responses submitted January 30, 2003 (page 21, first full paragraph) and November 1, 2004 (page 11, third full paragraph).

Hunter is cited by the Examiner to show Barondess et al. inherently disclose a pharmaceutically acceptable carrier:

> "the prior art *E. coli* host cell expressing the Iss polypeptide fragment or subunit . . . inherently contains *E. coli* lipopolysaccharide, which lipopolysaccharide is known in the art to serve as an intrinsic adjuvant (i.e., pharmaceutically acceptable carrier). For example, Hunter taught that gram negative bacterial lipopolysaccharide serve as immunomodulating agents and immunological adjuvants (see first sentence under Example 17 of Hunter). Clearly, the prior art *E. coli* host cell expressing the *Iss* polypeptide or subunit . . . and comprising the endogenous lipopolysaccharide adjuvant serves as an immunogenic composition and anticipates the instantly claimed product."

Office Action at page 6, emphasis added.

The toxicity of lipopolysaccharide is well known, and the text of Hunter referenced by the Examiner acknowledges this:

> "It has long been recognized that lipopolysaccharides from gram negative bacteria are effective immunomodulating agents and immunologic adjuvants. However, the toxicity of these materials has impeded their development as adjuvants."

Hunter, col. 28, lines 30-33, emphasis added (also see Hunter at col. 5, lines 13-17).

There is "a clear definition in the specification" (M.P.E.P §2111.01) of pharmaceutically acceptable carrier as "a carrier(s) that is 'acceptable' in the sense of being compatible with the other ingredients of a composition and not deleterious to the recipient thereof." (specification at page 44, lines 14-16, emphasis added). Since lipopolysaccharide is toxic, it cannot be considered to be a pharmaceutically acceptable carrier. Thus, Hunter cannot be used to show that Barondess et al. inherently discloses the claimed composition comprising a pharmaceutically acceptable carrier.

Furthermore, "[i]n relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art" (emphasis in original). M.P.E.P §2112. The Examiner cannot make that showing here. The doctrine of inherency is not available to supplement the demonstrated deficiencies of Barondess et al.

Accordingly, Applicants submit that Barondess et al. clearly fails to teach each and every element of independent claim 37 and, thus, fails to satisfy the objective criteria required to anticipate that claim. It is further submitted that claims 15-23 are novel in view of their dependence. Review and withdrawal of this rejection are respectfully requested.

Rejection of claim 41

Claim 41 stands rejected under 35 U.S.C. §103(a) as unpatentable over Barondess et al. as applied to claim 37 above and further in view of Applicant's admitted state of the art.

This rejection is identical, word for word, with the rejection present at pages 7-8, paragraph 20, in the previous (sixth) Office Action (dated August 10, 2005). However, the present (seventh) Office Action states at page 3, paragraph 8, that this rejection is withdrawn.

Since the Examiner withdrew this rejection in view of arguments presented by the Applicants, and the Examiner has not presented any additional argument to support a prima facie case of obviousness, Applicants submit that the Examiner has not met the burden of establishing a prima facie case of obviousness. Review and withdrawal of this rejection are respectfully requested.

Rejection of claims 42 and 68

Claims 42 and 68 stand rejected under 35 U.S.C. §103(a) as unpatentable over Barondess et al. as applied to claim 38 above and further in view of Krieg et al.

With respect to claim 42,this rejection is identical, word for word, with the rejection present at pages 8-9, paragraph 21, in the previous (sixth) Office Action (dated August 10, 2005). However, the present (seventh) Office Action states at page 3, paragraph 9, that this rejection of claim 42 is withdrawn.

Since the Examiner withdrew this rejection in view of arguments presented by the Applicants, and the Examiner has not presented any additional argument to support a prima facie case of obviousness, Applicants submit that the Examiner has not met the burden of establishing

a prima facie case of obviousness. Review and withdrawal of this rejection of claim 42 are respectfully requested.

With respect to claim 68, please refer to the earlier submitted argument in the response submitted November 10, 2005, specifically page 14, last paragraph, through page 15. Although this earlier submitted argument relates to claim 42, both claims 42 and 68 recite "an immunostimulatory sequence," and the present rejection of claim 68 is based on this recitation.

Since the Examine rhas not established a prima facie case of obviousness, review and withdrawal of this rejection of claim 68 are requested.

Summary

It is respectfully submitted that the pending claims are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted

By
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
Phone: (612) 305-1220
Facsimile: (612) 305-1228
Customer Number 26813

June 8, 2006
Date

By: David L. Provence
David L. Provence
Reg. No. 43,022
Direct Dial (612) 305-1005

CERTIFICATE UNDER 37 CFR §1.8:
The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to **Mail Stop Amendment**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 8th day of June, 2006, at 2:45pm. 2:54pm (Central Time).

By: Rachel Gaglindi-Grasa Name: Rachel Gaglindi-Grasa